



Food and Drug Administration
Rockville MD 20857

Re: Androderm®
Docket No. 95E-0420

FEB 22 1996

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

#13

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,983,395 filed by TheraTech Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is Androderm® (testosterone), which was assigned New Drug Application (NDA) No. 20-489.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product. The attached list includes products that have been previously approved and contain the same active ingredient, testosterone, as in Androderm®.

The NDA was approved on September 29, 1995, which makes the submission of the patent term extension application on November 24, 1995, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Antoinette F. Konski
Morrison & Foerster
755 Page Mill Road
Palo Alto, CA 94304

**Previously Approved Products Containing the Active Ingredient
Testosterone***

ORETON-F OINTMENT
PERANDRENAL OINTMENT
MALE SEX HORMONE INJECTION
TESTRYL INJECTION
TRIPLE HORMONE SUSPENSION/INJECTION
MYOSOL TESTOSTERONE
TESTODERM TESTOSTERONE TRANSDERMAL SYSTEM
TESTOSTERONE

* This list was compiled on January 24, 1996.